REMARKS

Response to Restriction Requirement and Election

The Examiner has made a four-way restriction requirement as follows:

I. Claim 10, drawn to a pharmaceutical composition comprising

a) AZD2171 or a salt thereof excluding an AZD2171 maleate salt, and

b) a taxane in association with a pharmaceutically acceptable excipeint or carrier. If this Group is elected, then the below Summarized Species Election is also required.

II. Claim 11, drawn to a kit. . If this Group is elected, then the below Summarized Species Election is also required.

III. Claims 12-16, drawn to a method for the production of an antiangiogenic and/or vascular permeability reducing effect in a warm-blooded animal. . If this Group is elected, then the below Summarized Species Election is also required.

IV. Claims 17-18, drawn to a method for treating a cancer involving a solid tumor in a warm-blooded animal. . If this Group is elected, then the below Summarized Species Election is also required.

(Action of October 17, 2007 at page 2).

In response to this Restriction Requirement, **Applicants elect the invention of Group I.**

Having elected the invention of Group I, it is understood that the "below Summarized Species Election" requires that Applicants "elect a single taxane species for purposes of examination, e.g. paclitaxel." In response to this requirement for election of species, **Applicants provisionally elect the species docetaxel**. Claim 10 and new claims 19-23 are readable on the elected species.

It is understood that this election of species is provisional, in that the Examiner notes that upon the allowance of a generic claim, applicant will be entitled to consideration of claims to that additional species which depend from or otherwise require all the limitations of the allowable generic claim.

The Examiner notes at page 5 of the Action that where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend or otherwise require all limitations of the allowable product claim will be considered for rejoinder. The Examiner further notes at page 6 of the Action that, in the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn and the rejoined process claims will be fully examined for patentability. The Examiner further notes that to be entitled to rejoinder the withdrawn process claims must be amended during prosecution to require the limitations of the product claims; that failure to do so may result in a loss of the right to rejoinder; and that withdrawal of the restriction requirement will remove the protection of 35 U.S.C. 121 against double patenting rejections.

Accordingly, non-elected process claims 12-18 have been maintained in this application but indicated as being "withdrawn," and have been amended as needed to remain commensurate in scope with the amended composition of the elected claims.

Claim Amendments

Claims 1-9 are previously cancelled, and claim 11 (Group II) has been newly cancelled as being non-elected pursuant to the restriction requirement.

Independent composition claim 10 (Group I) has been elected and maintained, and new composition claims 19-24 have been added, which dependent claims are within the invention of elected Group I. As noted above, process claims 12-16 (Group III) and process claims 18-19 (Group IV) have been indicated as withdrawn but have been maintained in this application for purposes of rejoinder upon allowance of a composition claim commensurate in scope with the composition recited in such process claims.

Independent composition claim 10 has been amended to remove the recitation "excluding an AZD2171 maleate salt" as not being a needed limitation under U.S. practice. At page 3 of the present specification beginning at line 21 it is noted that:

> International Patent Application No. PCT/GB2004/005359 describes AZD2171 maleate salt and states that AZD2171 maleate salt may be applied as a sole therapy or may be used with one or more other substances and/or treatments. A list of other substances

> is given including taxoids of which Taxol® and Taxotere® are named.

International Patent Application No. PCT/GB2004/005359 was filed on December 18, 2004 and published as WO 2005/061,488 (hereinafter "McCabe WO '488") on July 7, 2005. The present application claims priority from GB 0406445.7 filed March 23, 2004 and is the US National Stage application of International Patent Application No. PCT GB2005/001089 filed March 22, 2005. Therefore the 35 U.S.C. 102(e) prior art effective date of McCabe WO '488 (which is its international filing date of December 18, 2004) is subsequent to the March 23, 2004 priority date to which the present application is entitled, and the publication of McCabe WO '488 on July 7, 2005 is subsequent to March 22, 2005 effective US filing date of the present application. Therefore, McCabe WO '488 is <u>not</u> prior art to the present application. Moreover, the corresponding U.S. application to McCabe WO '488 is US Application No. 10/581,279 (published as US 2007/0129387) directed toward maleate salts of AZD2171, but it does not *claim* any combination of AZD2171 or an AZD2171 maleate salt with a taxoid, and thus there should be no issue of obviousness-type double patenting between the present application and McCabe US Application No. 10/581,279. McCabe US Application No. 10/581,279 has been assigned to Examiner Truong in Group 1624, and according to PAIR as of this date the first Action is predicted in 7 months.

Although there are numerous recitations of embodiments throughout the present specification and claims (originating from the GB international application) that the maleate salt of AZD2171 is excluded, there is specific support in the application as filed for the *inclusion within the scope of this invention* of maleate salts within the generic description of salts of AZD2171 as well as specific claims to the presently claimed composition including a maleate salt of AZD 2171. See, *e.g.*, present specification page 18, lines 1-14, which states:

> The present invention relates to combinations of a taxane with AZD2171 or with a salt of AZD2171. A particular salt is an AZD2171 maleate salt.

> In particular the present invention relates to combinations of a taxane with a form of the AZD2171 free base.
>
> Salts of AZD2171 for use in pharmaceutical compositions will be pharmaceutically acceptable salts, but other salts may be useful in the production of AZD2171 and its pharmaceutically acceptable salts. Pharmaceutically acceptable salts may, for example, include acid addition salts. Such acid addition salts include for example salts with inorganic or organic acids affording pharmaceutically acceptable anions such as with hydrogen halides or with sulphuric or phosphoric acid, or with trifluoroacetic, citric or maleic acid. In addition pharmaceutically acceptable salts may be formed with an inorganic or organic base which affords a pharmaceutically acceptable cation. Such salts with inorganic or organic bases include for example an alkali metal salt, such as a sodium or potassium salt and an alkaline earth metal salt such as a calcium or magnesium salt.

Accordingly, it is respectively submitted that the amendment to claim 10 removing the unnecessary limitation "excluding an AZD2172 maleate salt" is proper and fully supported by the specification as filed.

New dependent claims 19-24 have been added. Dependent claims 19, 20 and 21 are directed toward the pharmaceutical composition comprising, respectively, a salt of AZD2171, an AZD2171 maleate salt, and an AZD2171 free base. Specification support for each of these claims is found, *inter alia*, at page 18, lines 1-14 as quoted above. Dependent claims 22-24 are directed toward the taxane comprising, respectively, a taxane selected from paclitaxel and docetaxel, docetaxel, and paclitaxel. Specification support for each of these claims is found in the specification, *inter alia*, at page 16, line 32 through page 17, line 2.

Method (process) claims 12, 13, 17 and 18, even though withdrawn, have been amended to remain commensurate with the composition scope of the elected claims as instructed by the Action. Support for this amended composition scope is as noted with respect to elected composition claim 10 above.

For the reasons noted above, all claim amendments are appropriate and find support in the specification as filed and therefore do not add new matter. Entry of these amendments is therefore believed to be in order and is respectfully requested. The above amendments are being made without waiver or prejudice to Applicant's right to pursue any subject matter deleted or withdrawn thereby in one or more divisional applications. Following entry of these amendments,

elected composition claims 10 and 19-24 remain pending in this application and non-elected method (process) claims 12-18 have been designated as withdrawn.

Conclusion

It is respectfully submitted that the Restriction Requirement has been fully and properly responded to and the claims have been appropriately amended in a manner consistent with the Action and the election. Accordingly, this application is now believed to be in condition for a favorable Action on the merits.

EXCEPT for issue fees payable under 37 C.F.R. § 1.18, the Director is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully Submitted,
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